

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Health Care Committee

BILL: PCS/SB 690

SPONSOR: Health Care Committee and Senator Lynn

SUBJECT: Immunizations

DATE: March 7, 2005

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HE	Pre-meeting
2.				
3.				
4.				
5.				
6.				

I. Summary:

The proposed committee substitute prohibits, on or after July 1, 2006, a woman who is knowingly pregnant or a child who is younger than 3 years of age from being vaccinated with a vaccine that contains mercury or injected with a product that contains more than 0.5 micrograms of mercury per 0.5-milliliter dose. The bill also prohibits, on or after July 1, 2006, a woman who is knowingly pregnant or a child who is younger than 3 years of age from being vaccinated with an influenza vaccine that contains more than 1 microgram of mercury per 0.5-milliliter dose.

If the Secretary of Health (the State Health Officer) declares a public health emergency and finds that an epidemic or shortage of supply of a vaccine will prevent knowingly pregnant women and children younger than 3 years of age from receiving the needed vaccine, the State Health Officer may authorize the administration of a vaccine that contains more mercury than the maximum level established in the bill.

This bill creates one undesignated section of law.

II. Present Situation:

Thimerosal in Vaccinations

Regulations adopted by the United States Food and Drug Administration (FDA) require the addition of a preservative to multi-dose vials of vaccines.¹ Thimerosal is a mercury-containing compound that has been used as a preservative in a number of biological and drug products, including vaccines. Thimerosal acts as a preservative and helps prevent potentially life

¹ See 21 CFR 610.15(a)

threatening contamination with harmful microbes. Concerns regarding the use of thimerosal and other mercury-containing compounds in vaccines and other products have been raised recently, and the FDA has worked with, and continues to work with, vaccine manufacturers to reduce or eliminate thimerosal from vaccines. Thimerosal has been removed or reduced to trace amounts in all vaccines recommended for children 6 years of age and younger, with the exception of inactivated influenza vaccine. A preservative-free version of the inactivated influenza vaccine is available in a limited supply. Some vaccines, such as the vaccine for tetanus, are available in formulations that are free of thimerosal.

The Institute of Medicine's Immunization Safety Review Committee, in its 2001 report, concluded that the evidence is inadequate to either accept or reject a causal relationship between thimerosal exposure from childhood vaccines and the neurodevelopmental disorders of autism, attention deficit hyperactivity disorder, and speech or language delay.² The committee report indicated that an effort to remove thimerosal from vaccines was a prudent course to reduce mercury exposure of infants and children as much as possible. Again, in 2004, the committee concluded that the scientific evidence favors rejection of a causal relationship between vaccines containing thimerosal and autism.

The FDA is continuing its efforts to reduce the exposure of infants, children, and pregnant women to mercury from all sources. Manufacturers are working to increase the supply of thimerosal-reduced and thimerosal-free vaccines used to vaccinate children and pregnant women against the influenza virus.

According to officials at the Department of Health, vaccines which contain thimerosal or mercury that are administered to children include: Diphtheria-Tetanus (DT), Tetanus-Diphtheria (Td), Influenza, and Meningococcal vaccine. An estimated 1300 children in Florida potentially have a medical contraindication to the major vaccine series: Diphtheria and tetanus toxoids and acellular pertussis (DTaP) due to the pertussis (whooping cough) component. The children who have a medical contraindication to the major vaccine series are routinely vaccinated with either DT or Td vaccine. The completion of this series is necessary for school and child care center attendance in Florida and is required for protection against diphtheria and tetanus. In addition, adolescents, prior to entering middle school, are required to receive a Td booster dose for increased protection. These children are currently vaccinated with the only product on the market and this product contains thimerosal or mercury. The benefits of immunizing these children against vaccine-preventable diseases outweigh the risks, according to medical recommendations.

The Advisory Committee on Immunization Practices recommends vaccinating children against influenza disease. A formulation of influenza vaccine that contains mercury or thimerosal as a preservative and a formulation that is preservative-free are available.

Public Health Emergencies

The State Health Officer may declare public health emergencies and issue public health advisories in accordance with s. 381.00315, F.S. Before issuing any health advisory, the State Health Officer must consult with any state or local agency regarding areas of responsibility

² See "Thimerosal in Vaccines" at <<http://www.fda.gov/cber/vaccine/thimerosal.htm>>.

which may be affected by the advisory. After determining that the public health advisory is necessary to protect the public health and safety, and before issuing the advisory, the State Health Officer must notify each county health department within the area which is affected by the advisory of the State Health Officer's intent to issue the advisory. The State Health Officer may take any action appropriate to enforce any health advisory.

Under s. 381.00315, F.S., "public health advisory" is defined to mean any warning or report giving information to the public about a potential public health threat. A "public health emergency" is defined to mean any occurrence, or threat, thereof, whether natural or man made, which results or may result in substantial injury or harm to the public health from infectious disease, chemical agents, nuclear agents, biological toxins, or situations involving mass casualties or natural disasters. The State Health Officer is required to consult with the Governor and to notify the Chief of Domestic Security Initiatives before declaring a public health emergency. A declaration of a public health emergency may only continue for 60 days unless the Governor concurs in the renewal of the declaration.

Upon the declaration of a public health emergency the State Health Officer may take actions that are necessary to protect the public health. Section 381.00315, F.S., specifies some of the actions that the State Health Officer may take upon the declaration of a public health emergency. The State Health Officer may order an individual to be examined, tested, vaccinated, treated, or quarantined for communicable diseases that have significant morbidity or mortality and present a severe danger to public health. Any individual, who is unable or unwilling to be examined, tested, vaccinated, or treated for reasons of health, religion, or conscience may be subjected to quarantine.

III. Effect of Proposed Changes:

The proposed committee substitute prohibits, on or after July 1, 2006, a woman who is knowingly pregnant or a child who is younger than 3 years of age from being vaccinated with a vaccine that contains any mercury or injected with a product that contains more than 0.5 micrograms of mercury per 0.5-milliliter dose. The bill also prohibits, on or after July 1, 2006, a woman who is knowingly pregnant or a child who is younger than 3 years of age from being vaccinated with an influenza vaccine that contains more than 1 microgram of mercury per 0.5-milliliter dose.

If the State Health Officer declares a public health emergency under s. 381.00315, Florida Statutes, and finds that an epidemic or shortage of supply of a vaccine will prevent knowingly pregnant women and children younger than 3 years of age from receiving the needed vaccine, the State Health Officer may authorize the administration of a vaccine that contains more mercury than the maximum level established in the bill for vaccination of knowingly pregnant women or children younger than 3 years of age.

The bill provides an effective date of upon becoming a law.

IV. Constitutional Issues:**A. Municipality/County Mandates Restrictions:**

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

Infants, children, and pregnant women may have some health benefits from a reduced exposure to mercury under the bill.

C. Government Sector Impact:

The Department of Health reports that it currently orders preservative-free influenza vaccine for children aged 6 to 35 months, therefore there is no fiscal impact associated with supplying vaccine to this age group. The Department of Health officials indicated that the 2004/2005 federal contract cost for Aventis–Pasteur preservative-free influenza vaccine is \$10.00 per dose. The 2004/2005 federal contract cost for Aventis–Pasteur preservative-containing vaccine is \$6.80 per dose. The department noted that it could not estimate the number of pregnant women who need to be vaccinated against influenza and therefore could not accurately estimate any additional costs associated with the use of only preservative-free influenza vaccine or influenza vaccine that contains no more than 1 microgram per 0.5-milliliter dose.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The Department of Health officials note that the bill would prohibit vaccinating pregnant women with the vaccine containing mercury even in the event of a potential influenza outbreak where

sufficient quantities of the preservative-free vaccine or vaccine that contains no more than 1 microgram of mercury per 0.5-milliliter dose may not be available. For vaccination of children aged under 3 years against influenza, the department, without a declaration of a public health emergency for a known threat, as well as other health care providers, would only be able to administer mercury-free vaccines or vaccines that contains no more than 1 microgram of mercury per 0.5-milliliter dose at a greater expense without a guarantee of vaccine supplies. According to the Department of Health, the FDA only approves preservative-free influenza vaccine for children aged 6 to 35 months.

The Department of Health also indicated that changes to immunization requirements would be necessary to ensure that those children who have contraindications to the pertussis component of the DTaP series receive a special exemption from the requirement of the bill to limit vaccination of children under the age of 3 to a vaccine that contains no more than 0.5 micrograms of mercury per 0.5-milliliter dose. Without the exemption, such children would remain susceptible to tetanus, pertussis, and diphtheria diseases.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.

VIII. Summary of Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.
